

K963450

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TAB F: 510(k) Summary of Safety and Effectiveness

Name, address, phone and fax numbers for person submitting the 510(k) notification:

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Device name:

<u>Trade name:</u>	Safety Vest, Economy Safety Vest, Vest with Shoulder Straps
<u>Common name:</u>	Same
<u>Classification name:</u>	Wheelchair Accessory

Predicate device:

Safety Vest, Economy Safety Vest, and Vest with Shoulder Straps marketed by Skil-Care Corporation.

Device Description:

Safety Vest: A vest-style, upper body device made from either woven polyester or polyester mesh. A 1 1/8-inch-wide polyester strap attached to one side of the vest at the waist is threaded through a slot on the other causing the vest to criss-cross and close in front of the patient. The waist strap secures to the kickspurs of the wheelchair or to the bed frame. The edges of the garment are finished with a bias cut binding, the color of which corresponds to a size chart included on the package insert. Device is intended for wheelchair or bed use.

Economy Safety Vest: Identical to above except that it is made from a lighter weight woven polyester material and is not available in polyester mesh. Unlike the above device which is intended for multiple uses, this is a single-patient-use device. This fact is noted on the garment label along with a notation that it is not to be laundered.

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Vest with Shoulder Straps: Identical with Safety Vest with the addition of 1 1/8-inch-wide webbing straps sewn to the shoulder area. These straps are secured to the pushhandles to provide patient posture support. This device is for wheelchair use only.

Indications for use:

Safety Vest is intended for patients who require restraint while in the wheelchair or bed.

Economy Safety Vest is intended for patients who require restraint while in the wheelchair or bed.

Vest with Shoulder Straps is intended for patients who require restraint and posture support while in the wheelchair.

Comparative information:

The device (devices) used for comparative purposes is (are) currently marketed as described in this submission. Device (devices) is (are): Safety Vest, Economy Safety Vest, Vest with Shoulder Straps.

These devices are currently exempt from 510(k) Premarket Notification Procedures and Good Manufacturing Practice Regulations and are legally marketed by Skil-Care Corporation as of the date of this submission. Skil-Care Corporation has been marketing and commercially distributing these devices for approximately 18 years.

The difference from our currently marketed devices are that the labeling will be changed to incorporate many of the suggestions in FDA's draft document, "Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints.

The use of all patient restraints in nursing homes are subject to Health Care Financing Administration's Regulations which prohibit the use of any restraint, physical or chemical, imposed for the purpose of discipline or convenience. Further, most health care facilities are accredited. HCFA rules governing appropriate use and accreditation standards for device use and personnel training provide the control necessary to ensure that the devices are used correctly. The application of these standards along with public awareness and health care provider training have contributed significantly to ensuring that the least restrictive restraint is used, that restraints are used only when needed for proper medical treatment, and that their use is under appropriate supervision.